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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,431	08/29/2001	Nathaniel Milton	342312003601	7457

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,431	MILTON ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *1-21,28,31-59 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27,29,30,60 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to preliminary amendment (filed 2/19/02), claims 53-62 have been added.

Applicants' election (filed 2/19/02) of Group 2 (claims 22-30) without traverse is acknowledged, as are the elected species (the species include polysorbate 80 as the surfactant, and mannitol as the bulking agent).

Claims 1-21 and 31-59 and 62 are withdrawn from consideration, pursuant to the restriction. In addition, claim 28 is withdrawn from consideration, since it does not encompass the elected surfactant. Claims 22-27, 29, 30, 60, 61 are examined in this Office action.

✧

The specification is objected to. On page 9, line 1, reference is made to US Patent 3,293,482. It is asserted (in the specification) that this patent describes a cyclic peptide. However, USP 3293482 has nothing to do with cyclic peptides, and moreover is unrelated to either chemistry or biology. This particular patent describes an amplifier tube for use in electronic applications. Correction of the specification is required.

✧

Claim 25 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites that "R" can be linoleoyl, palmitoyl, stearoyl, myristoyl, etc. Each of these terms means that a carbonyl group is included in the structure (at the C-1 position). As such, claim 25 would mandate that the group "R", taken together with the carbonyl group to which it is bonded, and further taken together with the imino group to which the carbonyl group is bonded, would represent an *alpha*-keto amide. It is rather unlikely that this is intended, but if it is, then the dependence of claim 25 on claim 24 would be improper. It is suggested (if consistent with intentions), that the following be recited:

> *R, taken together with the carbonyl group to which it is bonded, represents linoleoyl, palmitoyl, stearoyl, myristoyl, etc.*

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the

various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Andya (USP 6,267,958).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Andya discloses a freeze-dried formulation that comprises a therapeutic peptide, a micelle-forming surfactant, and a bulking agent. Relevant passages include those at col 15, line 36+, col 15, line 61+ and col 6, line 45+. The formulations are asserted (e.g., col 1, line 63+) to be stable. Also asserted is that a high protein concentration can be obtained by reconstituting the lyophilized compositions, yielding a reconstituted formulation that is also stable (col 1, line 66+). In addition, there are numerous references to mannitol.

Thus, it would have been obvious to use the echinocandin of the primary references in the formulations of Andya in order to achieve the advantages recited in Andya.

✧

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Horikoshi (USP 4348384).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Horikoshi discloses freeze dried liposomes that contain therapeutic proteins. Horikoshi is primarily concerned with blood coagulation proteins. The reference discloses that the formulations offer various advantages such as reduced susceptibility to decomposition in the GI tract. Mannitol is disclosed at col 2, line 27. Horikoshi does not suggest using the freeze dried formulation to administer an echinocandin.

However, it would have been obvious to use the echinocandin of the primary references in the formulations of Horikoshi in order to achieve the advantages recited in Horikoshi.

✧

Claims 22-27, 29, 30, 60 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Staniforth (USP 6,153,224).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Staniforth discloses dry powder formulations containing pharmaceutically active compounds such as peptides and proteins (col 7, line 44-56). There are several references to lecithin and phosphatidylcholine (e.g., col 5, line 43), which meet the requirement for a "micelle-forming surfactant".

Staniforth does not disclose echinocandins. Staniforth also does not use the term "freeze dried" or "lyophilized" to describe his formulations. However, the issue here is whether or not there is a physical difference that would arise if one were to take a formulation of Staniforth, add water, and then lyophilize the resulting aqueous mixture. In reality, there is no reason to expect any substantive change in the composition (as a consequence of hydration/dehydration). It is also noted also that Staniforth suggests a

milling procedure to reduce particle size. However, (a) the claimed formulations do not preclude a milling procedure, and (b) Staniforth does not require a milling procedure. Thus, the fact that such a milling procedure may be mentioned in the reference, but not explicitly mandated by the instant claims, does not impart novelty to the claimed invention.

Thus, it would have been obvious to use the echinocandin of the primary references in the formulations of Staniforth in order to achieve the advantages recited in Staniforth.

✧

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Tarara (USP 6565885)

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Tarara discloses pharmaceutical compositions which can contain (col 13, line 58) bioactive peptides. Freeze drying is disclosed at col 22, line 1. Incorporation of phosphatidylcholines is disclosed e.g., at col 10, line 31+, and the use of surfactants such as sorbitan trioleate is disclosed at col 10, line 59. Mannitol is disclosed at col

12, line 35. Tarara does not suggest using the freeze dried formulation to administer an echinocandin.

However, it would have been obvious to use the echinocandin of the primary references in the formulations of Tarara in order to achieve the advantages recited in Tarara.

✧

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Backstrom (USP 5,952,008).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Backstrom discloses peptide-containing compositions that can be obtained (col 8, line 60) by freeze-drying. The other requisite ingredients are disclosed as well, including several references to mannitol. Backstrom does not suggest using the freeze dried formulation to administer an echinocandin. However, it would have been obvious to use the echinocandin of the primary references in the formulations of Backstrom in order to

achieve the advantages recited in Backstrom.

✧

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Bernstein (USP 6,689,390).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Bernstein discloses pharmaceutical compositions which can contain (col 6, line 65) bioactive peptides. Freeze drying is disclosed at col 9, lines 39-41. Incorporation of phosphatidylcholines is disclosed e.g col 2, line 41+. Mannitol is disclosed at col 10, line 7, and col 10, line 18. Bernstein does not suggest using the freeze dried formulation to administer an echinocandin.

However, it would have been obvious to use the echinocandin of the primary references in the formulations of Bernstein in order to achieve the advantages recited in Bernstein.

✧

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Bouloumie (USP 6,284,277).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Bouloumie discloses freeze-dried pharmaceutical compositions. The presence of a bioactive protein is disclosed (e.g., col 19, line 47). In addition, there are several references to polysorbate 80 (e.g., col 19, line 11; col 19, line 29). The reference is also replete with references to mannitol. Bouloumie does not suggest using the freeze dried formulation to administer an echinocandin.

However, it would have been obvious to use the echinocandin of the primary references in the formulations of Bouloumie in order to achieve the advantages recited in Bouloumie

✧

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over

Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Weers (USP 6,309,623).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Weers discloses pharmaceutical compositions. These may be obtained (col 25, line 63+) by a freeze-drying process. The use of phosphatidylcholine is suggested, e.g., at col 16, line 53+. Mannitol is disclosed at col 18, line 36. Weers does not suggest using the freeze dried formulation to administer an echinocandin.

However, it would have been obvious to use the echinocandin of the primary references in the formulations of Weers in order to achieve the advantages recited in Weers.

✧

Claims 22-27, 29, 30, 60 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Staniforth (USP 6,475,523).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Staniforth discloses dry powder formulations containing pharmaceutically active compounds such as peptides and proteins (col 6, line 27). There are several references to lecithin (e.g., col 11, line 4; col 11, line 25), which meet the requirement for a "micelle-forming surfactant".

Staniforth does not disclose echinocandins. Staniforth also does not use the term "freeze dried" or "lyophilized" to describe his formulations. However, the issue here is whether or not there is a physical difference that would arise if one were to take a formulation of Staniforth, add water, and then lyophilize the resulting aqueous mixture. In reality, there is no reason to expect any substantive change in the composition (as a consequence of hydration/dehydration). It is also noted also that Staniforth suggests a milling procedure to reduce particle size. However, (a) the claimed formulations do not preclude a milling procedure, and (b) Staniforth does not require a milling procedure. Thus, the fact that such a milling procedure may be mentioned in the reference, but not explicitly mandated by the instant claims, does not impart novelty to the claimed invention.

It would have been obvious to use the echinocandin of the primary references in the

formulations of Staniforth in order to achieve the advantages recited in Staniforth

Claims 22-27, 29, 30, 60, 61 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Dellamary (USP 6433040).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Dellamary discloses pharmaceutical compositions which can contain (col 18, line 58) bioactive peptides. Freeze drying is disclosed at col 25, line 44+. Incorporation of phosphatidylcholines is disclosed e.g., at col 16, line 45+, and the use of surfactants such as sorbitan trioleate is disclosed at col 16, line 62. Mannitol is disclosed at col 18, line 25. Dellamary does not suggest using the freeze dried formulation to administer an echinocandin.

It would have been obvious to use the echinocandin of the primary references in the formulations of Dellamary in order to achieve the advantages recited in Dellamary.

✧

Claims 22-27, 29, 30, 60 are rejected under 35 U.S.C. §103 as being unpatentable over Debono (USP 4293489) or Burkhardt (USP 5,965,525) or Burkhardt (USP 5,932,543) or Chen (USP 5,198,421) or Balkovec (USP 5541160) or Abbot (USP 4,304,716) in view of Edwards (USP 5,985,309).

Each of the primary references (Debono, Burkhardt, Chen, Balkovec, Abbot) discloses echinocandins. None of the primary references discloses a freeze-dried formulation that comprises an echinocandin, a micelle-forming surfactant, and a bulking agent.

Edwards discloses pharmaceutical compositions which can contain (col 12, line 1) bioactive peptides. Freeze drying is disclosed at various locations including col 8, line 48; col 14, line 5, and col 16, line 23. Incorporation of phosphatidylcholines is disclosed e.g., at col 7, line 15, and the use of surfactants such as sorbitan trioleate is disclosed at col 7, line 60.

Edwards does not suggest using the freeze dried formulation to administer an echinocandin.

It would have been obvious to use the echinocandin of the primary references in the formulations of Edwards in order to achieve the advantages recited in Edwards.

✧

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1600